

## REMARKS

The present application is directed to methods comprising administration of compositions comprising mycobacterial cell wall extract for activating the immune system of an animal or enhancing production performance of the animal. In a preferred embodiment, the methods of the present invention involve the administration of compositions comprising mycobacterial cell wall extract from *Mycobacterium phlei*.

In an effort to facilitate prosecution, the specification has been amended and the following remarks are provided in response to the rejections raised in the April 14, 2004 Office Action. No new matter has been added and support for the amendments is found throughout the specification.

### *Specification*

In the April 14, 2004 Office Action, the Examiner requested amendment of the first line of the specification to read as follows: "This application is a 371 national phase application of PCT/US00/20013, filed July 21, 2000 which claims benefit of U.S. Provisional Application Serial No. 60/145,314, filed July 23, 1999." The appropriate amendment is entered herein.

### *Double Patenting*

In the April 14, 2004 Office Action, the Examiner rejected Claims 32-53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-19 of United States Patent No. 5,759,554 (hereafter '554). The Examiner stated that although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims encompasses methods of stimulating the immune system of an animal comprising administering a mycobacterial cell wall extract. Applicants had previously agreed to submit a terminal disclaimer once the claims are considered to be allowable. In an effort to facilitate prosecution, applicants have herein bifurcated the original claim set into two principal

claim sets. Accordingly, whereas there was previously one claim set directed to methods of activating the immune system of an animal or to enhance production performance of the animal, there is now (1) a claim set (Claims 32-53) directed to methods of activating the immune system of an animal and (2) another claim set (Claims 54-69) directed to methods for enhancing production performance of the animal. The nonstatutory double patenting rejections are addressed in light of the bifurcated claims.

*Claims 32-53: Methods of Activating the Immune System of an Animal*

*Nonstatutory Double Patenting Rejection over Claims 1-19 of U.S. Patent No. 5,759,554*

The Examiner had originally rejected the claims in the September 17, 2003 office action stating that although the conflicting claims of the present application and U.S. Patent No. 5,759,554 (hereafter '554) were not identical, they were not patentably distinct from each other because each set of claims encompassed methods of stimulating the immune system of an animal comprising administering a mycobacterial cell wall extract.

Applicants respectfully submit that the claimed compositions are not identical and that it would be readily apparent to one skilled in the art that two different mycobacterial cell wall extracts are involved. More specifically, the compositions of the '554 patent comprise "an aqueous suspension of an insoluble bacterial cell wall fraction that does not contain oil" (see all independent claims (numbers 1, 9, 11, and 13)). The present claims do not have the same limitation. The present compositions do contain oil (see for example specification page 8 lines 8-17: "...MCWE is mixed with a mineral oil or with a neutral oil...Examples include...squalene, ...soybean oil, canola oil, palm oil, olive oil and myglyol..."; see also Example 1 page 9, lines 31-37 and page 10 lines 1-17 wherein the MCWE emulsion is described as containing 2% squalene. Accordingly, applicants submit that the terminal disclaimer is not appropriate. Reconsideration and withdrawal of this rejection is respectfully requested.

*Nonstatutory Double Patenting Rejection over Claims 1-19 of U.S. Patent No. 5,632,995*

The Examiner rejected the claims in the Office Action of April 14, 2004, stating that although the conflicting claims of U.S. Patent No. 5,632,995 (hereafter '995) are not identical, they are not patentably distinct from each other because each set of claims encompasses methods of increasing reproductive performance of an animal comprising administering a mycobacterial cell wall extract prior to ovulation. Applicants respectfully traverse.

As amended herein, Claims 32-53 are directed to methods for activating the immune system not increasing reproductive performance. Accordingly, applicants submit that the terminal disclaimer is not appropriate. Reconsideration and withdrawal of this rejection is respectfully requested.

*Claims 54-69: Methods for Enhancing Production Performance of an Animal*

*Nonstatutory Double Patenting Rejection over Claims 1-19 of U.S. Patent No. 5,759,554*

The Examiner had originally rejected the claims in the September 17, 2003 office action stating that although the conflicting claims of the present application and U.S. Patent No. 5,759,554 (hereafter '554) were not identical, they were not patentably distinct from each other because each set of claims encompassed methods of stimulating the immune system of an animal comprising administering a mycobacterial cell wall extract. In light of the amendments herein, Applicants respectfully disagree.

As amended herein, new Claims 54-69 are directed to methods for enhancing production performance of an animal not stimulating the immune system. Accordingly, applicants submit that the terminal disclaimer is not appropriate. Reconsideration and withdrawal of this rejection is respectfully requested.

*Nonstatutory Double Patenting Rejection over Claims 1-5 of U.S. Patent No. 5,632,995*

The Examiner rejected the pending claims in the Office Action of April 14, 2004, stating that although the conflicting claims of U.S. Patent No. 5,632,995 (hereafter '995) are not

identical, they are not patentably distinct from each other because each set of claims encompasses methods of increasing reproductive performance of an animal comprising administering a mycobacterial cell wall extract prior to ovulation. Applicants respectfully traverse. The cited patent and the present application differ for at least three principal reasons: (a) recipient animal; (2) timing of administration of the composition; and (3) end result.

The methods of the '955 patent are directed to the treatment of a parent animal in an effort to affect conception, pregnancy and birth. In contrast, the methods of the present application, are directed to the treatment of the offspring in an effort to affect the quality of their survival.

The claims of the '955 patent mandate that the compositions be administered prior to ovulation. In contrast, the claims of the present application involve the administration of the compositions to the newborn animals between one hour and 28 days of age.

Applicants respectfully submit that whereas the '995 patent is directed to methods of increasing *reproductive* performance, the present application is directed to enhancing *production* performance. As would be evident to one skilled in the art, the cited patent is drawn to methods that result in an increase in *reproduction*. i.e., more offspring from treated adult females by increasing the number of pregnancies, fecundity of the pregnancy (number of litter-mates) and survival of the offspring. In addition, one skilled in the art would also interpret the '955 patent as being directed to increasing the number of animals conceived (i.e. long before they are born) by treating the mother. In essence, in the cited '955 patent the number of offspring refers to live births: the term offspring in this context is prospective and refers to a future live birth. The present application and claims are directed to methods for increasing the production of food (meat) from treated food production animals (treated after they are born) by increasing the survival of the neonatal offspring and/or by increasing growth rates, feed conversion and loss due to disease from the time of birth until slaughter. In contrast, the term offspring in the '995 patent is objective and refers to the actual animals that are born alive (i.e., live births).

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In conclusion therefore, whereas the animal treated in the '995 patent is a parent animal treated prior to ovulation for the purpose of improving conception/fertilization and live births, the animal treated in the present application is the offspring, treated after birth treated for the purpose of improving survival of that same animal. Accordingly, applicants submit that the terminal disclaimer is not appropriate and reconsideration and withdrawal of the claim rejections based on the judicially created doctrine of obviousness-type double patenting is respectfully requested.

### ***Conclusion***

For at least the above reasons, Applicants respectfully request allowance of Claims 32-69 and issuance of a patent containing these claims in due course. If there remain any additional issues to be addressed, the Examiner is urged to contact the undersigned attorney.

The foregoing is submitted as a full and complete response to the Office Action mailed April 14, 2004. Applicants respectfully submit that the claims are fully enabled, novel and non-obvious over the cited art. Applicants assert that the claims are now in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case, which may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned attorney at (404) 745-2463 is respectfully solicited.

Respectfully submitted,

  
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